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Guy Donaldson

December 14, 2005

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DEC 27 2005
Air/Toxics & Inspection
Coordination Branch
6EN-A

David Neleigh (6PD-R)
Region 6
Environmental Protection Agency
Fountain Place 12th Floor, Suite 1200
1445 Ross Avenue
Dallas, TX 75202-2733

Subject: Notification of Compliance for Sterigenics US, LLC's Santa Teresa, New Mexico Facility

Dear Mr. Neleigh:

As required per 40 CFR Part 63, Subpart O – NESHAP Ethylene Oxide Emissions Standards for Sterilization Facilities, attached is a notification of compliance status for Sterigenics US, LLC's Santa Teresa, NM facility. This notification of compliance status is signed by a responsible company official, who certifies its accuracy and attests that this facility has complied with the relevant rules and regulations.

If you have any questions on this notification, please call me at 323-586-9060.

Sincerely,

Rosey Liu
EH&S Engineer

Attachment: Notification of Compliance

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DEC 27 2005

Air/Toxics & Inspection
Coordination Branch
GEN-A

NOTIFICATION OF COMPLIANCE STATUS

Applicable Rule: 40 CFR Part 63, Subpart O – Ethylene Oxide Emissions Standards for Sterilization Facilities

Facility name and contact:

Sterigenics US, LLC – Santa Teresa Facility
2400 Airport Road
Santa Teresa, NM 88008

A. Method used to determine compliance:

A performance test was conducted to determine the facility's compliance with the NESHAP regulation. The test conformed to test methods presented in the applicable regulation (40 CFR Part 63, Subpart O).

B. Results of any performance tests, opacity or visible emission observations, continuous monitoring system (CMS) performance evaluations, and/or other monitoring procedures or methods that were conducted:

The annual source test for the catalytic oxidizer and scrubber was conducted on December 2, 2005. The Ceilcote scrubber used to control emissions from sterilization chambers showed 99.5% removal efficiency. The catalytic oxidizer system, used to control emissions from the aeration rooms, has an ethylene oxide emission reduction efficiency of 99.99% (40CFR63.362(d) requires reduction to a maximum concentration of 1 ppmv or by at least 99 percent, whichever is less stringent). Therefore, this test demonstrates that Sterigenics' Santa Teresa plant was in compliance with our air permit and the NESHAP regulation for ethylene oxide sterilization facilities.

C. Methods that will be used for determining continuing compliance, including a description of monitoring and reporting requirements and test methods:

In order to ensure continuing compliance, Sterigenics measures and records the catalytic oxidizer's catalyst bed temperature on a daily basis. We also monitor the scrubber liquor pH and level on a weekly basis.

D. Type and quantity of hazardous air pollutants emitted by the source (or surrogate pollutants if specified in the relevant standard), reported in units and averaging times and in accordance with the test methods specified in the relevant standard:

Our Santa Teresa facility uses greater than 10 tons of ethylene oxide per year to sterilize medical devices. In 2004, the plant used approximately 606,964 pounds of ethylene oxide. About 95% of the ethylene oxide used at the facility is discharged through the sterilization chamber vents (via vacuum pumps). For 2004, these sterilizer chamber vent emissions would be about 576,615 pounds. With 99.5% control efficiency for the acid-water scrubber, the resulting emissions from the scrubber would be about 2,883 pounds of ethylene oxide per year.

About 4% of the ethylene oxide used at the facility is discharged through the aeration rooms and 1% through the back vents. With an average 99.99% control efficiency for the catalytic oxidizer, the resulting emissions from the aeration vents would be about 2 pounds of ethylene oxide per year. Back vent emissions are not controlled.

E. Analysis demonstrating whether the affected source is a major source or an area source (using the emissions data generated for this notification):

Using emissions data for this notification, this facility can be considered an area source.

As presented above, this facility used about 606,964 pounds of ethylene oxide in 2004. The total emissions from the facility would be from the scrubber (which treats about 95% of the ethylene oxide used) and the catalytic oxidizer (which treats about 4% of the ethylene oxide used). In 2004, the total emissions would be 2,883 pounds from the scrubber and 2 pounds from the catalytic oxidizer (aeration room emissions). This would equate to about 2,885 pounds of ethylene oxide emissions from the source.

F. Description of the air pollution control equipment (or method) for each emission point, including each control device (method) for each hazardous air pollutant and the control efficiency:

The air pollution control equipment used to control the ethylene oxide emissions from the sterilizer chamber vents (from the vacuum pumps) is a wet-acid scrubber system, and from the aeration room, a catalytic oxidizer is used. This scrubber takes the ethylene oxide emissions and converts them to an aqueous ethylene glycol solution. As shown during the annual compliance testing, the catalytic oxidizer has a control efficiency of about 99.99% and the scrubber efficiency is 99.5%.

G. **Statement by the owner or operator of the affected existing, new, or reconstructed source as to whether the source has complied with the relevant standard or other requirements:**

To the best of our knowledge, the Santa Teresa facility has complied with the relevant NESHAP standard; 40 CFR Part 63, Subpart O.

Certification Statement:

To the best of the undersigned's knowledge, information, and belief formed after reasonable inquiry, the information submitted in this notification of compliance status for Sterigenics US, LLC's Santa Teresa, NM facility is true, accurate, and complete.

Kathleen Hoffman/RL
Signature

Kathleen Hoffman
Print Name

V.P. – RA/QA
Title

Dec. 14, 2005
Date